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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,495	09/15/2003	Yoshiyuki Shoji	H6807.0001/P001-A	7412

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EXAMINER

LEWIS, PATRICK T

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 06/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/661,495

Applicant(s)

SHOJI ET AL.

Examiner

Patrick T. Lewis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 February 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-31 is/are pending in the application.
- 4a) Of the above claim(s) 12-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date. 05132005.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I (claims 1-5 and 28-31) in the reply filed on July 22, 2004 is acknowledged.
2. Claims 12-27 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on July 22, 2004.
3. This application contains claims 12-27 drawn to an invention nonelected with without traverse in the reply filed on July 22, 2004. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Applicant's Response Dated February 7, 2005

4. In the Response filed February 7, 2005, claims 28 and 31 were amended. Claims 12-31 are pending. An action on the merits of claims 28-31 is contained herein below.
5. Applicant's arguments, filed February 7, 2005, with respect to the rejection(s) of claim(s) 28-31 under 35 U.S.C. 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Hansen et al. US 6,672,458 (Hansen).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 28-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Forsythe, Jr. et al. US 4,214,993 (Forsythe), Sauer et al. EP 0 969 090 A1 (Sauer), and Hansen et al. US 6,672,458 (Hansen) in combination.

Claims 28-31 are drawn to a nucleic acid purification method using a tip incorporating a solid phase containing a nucleic acid capturing agent, comprising the steps of: sucking and discharging the nucleic acid containing solution into and out of the tip by pressure change; contacting a nucleic acid containing solution with a solid phase; discharging the nucleic acid containing solution outside the tip; contacting a washing solution with the solid phase; discharging the washing solution outside the tip; and discharging air into the tip after discharging washing solution to that remaining liquid is discharged. Claim 29 recites an additional washing step. Claim 30 further

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comprises contacting an eluent with the solid phase after the discharging the remaining liquid and discharging the eluent outside the tip. Claim 31 further comprises blocking outflow of the solid phase by a blocking member provided on the tip.

Forsythe teaches an apparatus (nested spin column) and method for separating fluids (Figures 1-3; column 2, line 18 to column 4, line 66). An extraction cartridge **32** containing a separating column with a resin bed is separated from the nested stack and placed in a centrifuge rotor, in an orientation so that fluids are moved through the column by centrifugal force. The extraction cartridge is positioned radially inside of a circumferentially positioned first container or cup **32** and a second container or cup **36**. The bottom tip end of the extraction cartridge **16** is in the form of a nozzle **28** which is tapered to a general point. Spherical porous support **30**, made of a typical inert plastic, are placed at the top and bottom of the particular separating material **26** formed in the column to maintain the particles in place. Various materials may be used for the separating column. The centrifuge rotor has a capability of switching the fluid flow path from the exit of the separating column in the extraction cartridge such that the effluent from the extraction cartridge such that the eluent from the extraction cartridge may be passed by choice either to the first cup **32** or to the second cup **36**. The rotor used is a swinging bucket rotor capable of holding a plurality of sets of extraction cartridges, first cup, and second cups. The centrifugal force acting on the horizontal column forces the sample through the resin bed at a controlled flow rate. The materials to be extracted from the sample are retained by the resin while other materials pass through the column and are collected by the first cup. Next, wash solvent or reagent is delivered to the fluid

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distribution hub of the rotor. The wash is divided into equal aliquots and directed to the resin beds in each separating column and collected in each first cup. In this step the wash removes unabsorbed sample components from the resin bed. Centrifugal force passes residual wash to the first cup. Eluting solvent is dispensed from a solvent reservoir and aliquoted to the several cartridge positions. The solvent passes through the column of the extraction cartridge under the influence of centrifugal force, extracting the adsorbed materials which are eluted from the resin bed of the column and collected in the second cup. If desired, a pump (suction or pressure) may be used to move the fluid through the column. Compressed gas may be used as the driving force.

Forsythe differs from the instant invention in that: 1) Forsythe does not explicitly teach the purification of nucleic acids, 2) Forsythe does not explicitly teach additional washing steps, and 3) Forsythe is silent on the step of sucking and discharging the nucleic acid containing solution into and out of the tip by pressure change; however, the deficiencies of Forsythe would have been obvious in view of Sauer and Anderson.

Sauer teaches a method for isolating plasmid DNA from bacterial overnight cultures (column 10, lines 1-44). The method comprises: a) applying the sample to the spin column; b) centrifuging for 1 minute and discarding the flow-through; c) washing the column, centrifuging for 1 minute, and discarding the flow-through; d) washing the column, centrifuging for 2 minutes, and discarding the flow-through; and e) eluting the DNA.

Hansen teaches a sample assay preparation system **100** for which a nucleic acid molecule extractor **102** is adapted for use (column 4, lines 22-33; FIG. 1). The system

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100 includes a robot **104**. The robot includes a pipette holding mechanism **106**, which can releasably couple to a plurality of pipette tips stored in pipette tip racks **108**. The robot **104** further includes a suction mechanism (not shown) that can be activated to create a vacuum to draw fluid into the pipette tips, or to create pressure to eject fluid from the pipette tips. Initially, samples containing cells are provided in sample input tubes **112** (column 6, lines 32-56). These samples may be of any type, including biological fluids such as blood, urine and cerebrospinal fluid, tissue homogenates and environmental samples, that are to assayed for nucleic acids of interest. The robot **104** is controlled to position the pipette tips over a respective number of sample tubes **112** and draw the samples into the respective pipette tips. The robot then moves the pipette tips over to the extractor **102**, and releases the samples into respective sample tubes **120** that have been loaded in advance into the rack **118** positioned on the extractor **102**.

It would have been obvious to one of ordinary skill in the art at the time of the invention to purify a nucleic acid containing solution using the nested spin column taught by Forsythe. Spin columns are routinely used to purify nucleic acids as demonstrated by Sauer. The selection of a suitable conventional purification technique such as chromatography is well within the purview of one of ordinary skill in the art. It would have also been obvious to one of ordinary skill in the art at the time of the invention to perform multiple washings as taught by the prior art. One would have been motivated to do so in order to achieve greater purity of the product. It would have also been obvious to one of ordinary skill in the art to suck and discharge the nucleic acid containing solution into and out of the tip by pressure change as taught by Hansen.

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One of ordinary skill in the art would have been motivated to do so in order to increase the number of samples capable of being analyzed.

Conclusion

9. Claims 12-31 are pending. Claims 12-27 are drawn to a nonelected invention. Claims 28-31 are rejected. No claims are allowed.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick T. Lewis whose telephone number is 571-272-0655. The examiner can normally be reached on Monday - Friday 10 am to 3 pm (Maxi Flex).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Patrick T. Lewis, PhD
Examiner
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